

4-1-2006

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Recommended Citation

Seán M. Coughlin, *The Newman Application and the USPTO's Unnecessary Response: Patentability of Humans and Human Embryos*, 5 Chi.-Kent J. Intell. Prop. 90 (2006).

Available at: <http://scholarship.kentlaw.iit.edu/ckjip/vol5/iss2/1>

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THE NEWMAN APPLICATION AND THE USPTO'S UNNECESSARY RESPONSE

PATENTABILITY OF HUMANS AND HUMAN EMBRYOS

Seán M. Coughlin*

Background

Inventor Stuart Newman filed an application drawn to human/animal chimeric organisms, embryos and methods of making and using the same.¹ Newman's application was not necessarily filed to acquire a patent on this invention, but to serve as a *de facto* petition to the U.S. Patent and Trademark Office (USPTO) to clarify the Office's stance on the patentability of this and similar controversial inventions.² Newman opposes patenting such inventions, because they could lead to the unethical use and treatment of human animal chimeras, *e.g.* in drug testing.³ The USPTO, while refusing to give Newman an advisory opinion, and despite having plenty of other more mundane reasons to reject the Newman application⁴, accommodated him by rejecting his claims for not being drawn to a statutorily permitted subject matter, *i.e.* stating that claims "embracing" humans and human embryos are not patentable.⁵

The primary basis of this rejection was an interpretation of Congress' intent regarding patenting humans,⁶ which was later confirmed by the addition of a provision to the Consolidated Appropriations Act of 2004, forbidding the patenting of "human organisms".⁷ While the rationale for this rejection is plausible, it and the legislation are unnecessary and problematic. There is no need to specifically prevent the patenting of a human being or a human embryo. First, human beings and embryos are unpatentable subject matter in any case because they are not novel or made by man, as required for patentability.⁸ Second, there is currently no commercial reason to patent a genetically modified near-human. If a reason develops, laws should be enacted to deal with the specific organism created in response to that reason. Third, preventing patent coverage of humans, without even a precise definition of what a "human" entails in the patent law, does not prevent people from making and patenting ethically

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¹ U.S. Application Serial No. 08/993,564 (filed on December 18, 1997) [hereinafter U.S.S.N. 08/993,564], and divisional application U.S. Application Serial No. 10/308,135 (filed on December 3, 2002). The specifications are substantively identical.

² *Id.*

³ Stuart A. Newman. *The human chimera patent initiative*, MED. ETHICS 9(1), 4 and 7 (Winter 2002).

⁴ The claims were rejected for anticipation, obviousness, lack of enablement, written description and utility. See generally the File History of U.S.S.N. 08/993,564.

⁵ See file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004.

⁶ See the File History of U.S.S.N. 08/993,564, non-final Office Action mailed on October 7, 2003 at 17.

⁷ Pub. L. No. 108-199, § 634, 118 Stat. 101.

⁸ "The laws of nature, physical phenomena, and abstract ideas have been held not patentable... Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." *Diamond v. Chakrabarty* 447 U.S. 303, 309 (1980).

questionable inventions in this area and chills invention in areas that may be considered drawn to “humans” including those that are not ethically questionable. For example, Harvard’s oncomouse patent encompassed a genetically engineered mouse with human genes. Today, it is considered much less controversial than inventions drawn to inventions which are drawn to uses of human embryos.

This note describes first the subject matter and prosecution of the Newman Application, showing that there were many other more mundane reasons to reject his claims, rather than impose a ban on claims “embracing a human.” Newman used his application as a *de facto* petition to the USPTO, and despite not allowing such petitions, the USPTO gave Newman the ruling that he wanted. Second, the USPTO did not have statutory support to make the rejections it did at the time of the filing of the Newman Application. Despite the passage of an amendment to the Appropriations Act of 2004, which explicitly disallowed the patenting of humans, it is unclear what the scope of the term “human organism” is. Third, this note describes the policy reasons for not making a *per se* ban of patents on humans.

Twenty-five years ago in *Diamond v. Chakrabarty*⁹, the Supreme Court first ruled that organisms were patentable subject matter.¹⁰ The respondents in *Chakrabarty* suggested that such a ruling would subject us to a “parade of horrors,” with the patentability of organisms providing incentive to create new ones with developing technologies.¹¹ At present, despite the available technology to construct human/animal chimeras existing for 18 years¹², this parade of horrors has not yet come to pass. As suggested by the court in *Chakrabarty*, the legislature provides a better forum for deciding whether a technology is patentable subject matter than the Patent Office.¹³ However, the legislature cannot draft laws to prohibit organisms that do not exist. Decisions on patentable subject matter should be made on the basis of the actual subject matter, not on the fear of the implications of their possibility.

I. The USPTO’s Overzealous Response to the Newman Application

Newman’s specification puts forth the abstract idea of a human/animal chimera.¹⁴ The Background section of the application provides methods of making animal chimeras (*e.g.* sheep/goats or “geeps”) that have been known in the art for years. These methods had never been used to make human hybrids. Newman’s application suggests that these methods, previously used on geeps should be transferable to human/animal chimeras without undue experimentation.¹⁵ The “Objects of the Invention” and “Detailed Description” sections of his application give specific examples of the animals used, *i.e.* humans and primates.¹⁶ These

⁹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹⁰ *Id.* at 303.

¹¹ *Id.* at 317.

¹² At least as suggested by Newman. See the Background of the Invention in the specification of U.S.S.N. 08/993,564.

¹³ *Chakrabarty*, 447 U.S. at 317.

¹⁴ See the specification of U.S.S.N. 08/993,564, throughout the Summary of the Invention and the Detailed Description of the Embodiments, *e.g.* at 16, lines 13-19.

¹⁵ *Id.* at the Background, Summary of the Invention and Detailed Description of the Preferred Embodiments. All of the methods for making the chimeras of the invention are described in the Background. The Summary and Description simply suggest the imposition of the cells of different organisms, especially humans.

¹⁶ *Id.*

sections also provide utilities for these chimeras like embryonic toxicology, teratology, and methods for making organs for transplant into humans.

Even without the ethically controversial nature of Newman's invention, from his specification, it seems that Newman does not have a patentable invention at all. He provides the idea of using techniques already know in the art, to create human chimeric clones, but never bothers to iron out the technical details crucial for making cloning in a new species functional. This is because his reasons for filing are not to put forth or protect an "invention", but to put the Patent Office on the spot, to decide whether this sort of invention would be patentable or not.

A. Newman's Intention in Filing His Application Was to Clarify USPTO Policy and Bring Attention to that Policy.

Newman stated that his purpose for filing his application was to spur debate about the ethics of genetic engineering and patenting life forms.¹⁷ In an article written for *Medical Ethics*¹⁸ Newman explained, "It is clear... that biotechnology is capable of producing items that, while legal and eminently useful, could nonetheless conflict with other cultural values, and would therefore be considered immoral and undesirable by many people."¹⁹

Newman has been accused of scaremongering, with the reasoning being that scientists would never make the monsters of which Newman is so afraid.²⁰ However, Newman has responded that scientists already have acquired patents on such inventions. Advanced Cell Technology has obtained a patent on a technique for creating cloned embryos produced from human cell nuclei and cow eggs.²¹ Further, Geron Corporation, which held licenses for patents to embryonic stem cells, acquired the Scottish company that cloned Dolly the sheep.²² Newman worries that these companies and others have set the ground work for human cloning to begin without any guidelines on what lines the researchers could not cross.²³ He asserts that, as a result, "the public could quickly accommodate itself to fabricated humans and near-humans, organisms that previously existed only in the realm of speculative fiction."²⁴ Newman seems to think that without guidelines, the country will return to an ethical situation akin to that of slavery in pre Civil War America, with genes and ontogeny being the discriminatory factors instead of race.

Newman's primary worry about human cloning is that, once breakthroughs were made using the cloning technology he described in his application, "production of quasi-humans for research or therapy... cannot be too far behind."²⁵ Human cloning in the United States is currently legal. At the time Newman was writing his article, H.R. 1644, outlawing human

¹⁷ B.D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 693 (2004).

¹⁸ See Newman, *supra* note 3.

¹⁹ *Id.* at 4.

²⁰ <http://www.intelliwareint.com/gls-cdrom/GLSPapers/Newman.htm> (Newman claims that Philip Leder, one of the inventors of Harvard's Oncomouse, accused him of scaremongering.)

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

cloning, was before the Senate.²⁶ However, this bill has never passed.²⁷ Thus, the invention claimed in Newman's application would have been legal to make, use and sell if a patent had issued.

Newman made an explicit petition to the Patent Office to clarify the Office's policy due to cloned or genetically modified human embryos near the beginning of prosecution of the Newman application.²⁸ The Office responded it does not give advisory opinions, and that patentability was decided by the Examiner and the Board of Appeals, and not petitionable.²⁹ Further, counter to the strategy of most patent applicants,³⁰ Newman, apparently revealed the subject matter of his application to ABC News, Nature, and the Washington Post, prompting a media advisory from the Patent Office on April 2, 1998, regarding the application.³¹ The media advisory stated, "It is the position of the USPTO that inventions directed to a human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement."³² Further, then Commissioner Lehman publicly stated that no half-human monsters would be patented or any other immoral inventions.³³ Newman responded with another petition complaining that applications were supposed to be kept in secret and that the Patent Office should not be making statements which would affect the patentability of their application to the public.³⁴ The petition was summarily dismissed.³⁵

Clearly, Newman wanted the USPTO to assure him that his nightmare invention was unpatentable by its very "immoral" nature. The USPTO responded that it was not in the business of giving advisory opinions. The USPTO only decides the patentability of individual applications, and does not give declaratory opinions upon request. All decisions made by the USPTO apply only to the specific facts of the patent application for which the decisions were made. However, despite its ability to reject his application for mundane reasons, the USPTO ultimately gave an opinion, following the policy measures it publicly announced upon the filing of Newman's application.

²⁶ R. Weiss, *U Firm Aims To Clone Embryos for Stem Cells*, WASHINGTON POST, July 11, 2001, at A1.

²⁷ Shawn E. Petersen, *A Comprehensive National Policy to Stop Human Cloning: An Analysis of the Human*, 17 Notre Dame J.L. Ethics & Pub. Pol'y 217, 223 (2003).

²⁸ File History of U.S.S.N. 08/993,564, Petition under 37 C.F.R. § 1.182 filed on February 25, 1998.

²⁹ *Id.* Decision on Petition mailed on May 26, 1998.

³⁰ At the time, the subject matter of patent applications was kept secret until the patent issued. Now, in most cases, the patent is only kept secret until publication 18 months after the earliest effective filing date. Inventors would generally prefer to keep their inventions secret to prevent competitors from beginning efforts to design around their inventions.

³¹ File History of U.S.S.N. 08/993,564, Petition under 37 C.F.R. § 1.182 filed on November 24, 1998.

³² *Id.* Affidavit filed with petition on November 24, 1998.

³³ M. Dowie, *Gods and Monsters*, MOTHER JONES, (Jan. - Feb. 2004), at http://www.motherjones.com/news/feature/2004/01/12_401.html.

³⁴ File History of U.S.S.N. 08/993,564, Petition under 37 C.F.R. § 1.182 filed on November 24, 1998.

³⁵ *Id.* Decision on Petition mailed on March 1, 1999.

B. Newman's Application was Unpatentable For Mundane Reasons and Did not Have to be Rejected for Having Claims Drawn to Humans.

The Newman Application was filed on December 18, 1997 and assigned U.S. Serial No. 08/993,564. During prosecution, Newman's application was rejected for a number of reasons, including anticipation, lack of enablement, lack of written description and lack of specific, substantial or credible utility.³⁶ Newman asserted that he had never actually made his human/animal chimeras; he simply asserted that they were possible to make using technology that already existed.³⁷ Newman stated, correctly that he was not required to actually make his invention for it to be patentable.³⁸ Regardless, Newman did not provide enough disclosure to have a patentable invention.

Newman's application is, at best, a suggestion to apply past techniques to human/animal chimeras, whereas previously they had only been applied to chimeras of different species of animals. There is no doubt that if a group of those skilled in the art were to apply themselves to this project, they would eventually be able to make the monstrous chimeras included in the vast genus of chimeras that Newman claims in his application, but it would require undue experimentation to develop these chimeras from the disclosure of Newman's application, rendering his claims unpatentable.

For an invention to be properly enabled, one of ordinary skill in the art would have to be able to make and use the invention, without undue experimentation.³⁹ In *In re Wands*⁴⁰, factors were promulgated by the appeals court to define undue experimentation.⁴¹ These factors are, "1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability or unpredictability of the art, and 7) the breadth of the claims."⁴² The Examiners,⁴³ in their Office Actions, stated that the art cited by Newman to demonstrate how to make and use his invention showed unpredictability.⁴⁴ The geeps of the prior art were not necessarily chimeric throughout.⁴⁵ Some of them had chimeric coats/skin and or blood, but many of the offspring of these purported chimeras were not chimeric at all.⁴⁶ The Examiner found that since the methods used created such disparate results; one of ordinary skill in the art would have to use undue experimentation to make the human/animal chimeras suggested in Newman's application.⁴⁷

Aside from putting forth references describing specific interspecies animal chimeras, Newman's patent specification gives little or no direction on how to make or use his chimeras.

³⁶ See file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004.

³⁷ See Newman, *supra* note 3.

³⁸ *Id.* at 4.

³⁹ 35 U.S.C. § 112 (2000), first paragraph.

⁴⁰ *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

⁴¹ *Id.* at 737.

⁴² *Id.*

⁴³ A number of Examiners had been assigned and subsequently removed from this case.

⁴⁴ See, e.g., file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004 at page 11.

⁴⁵ *Id.*

⁴⁶ *Id.* at 10-11.

⁴⁷ *Id.*

Newman wrote his specification this way on purpose, since he did not want to disseminate information that would actually allow people to practice the invention.⁴⁸ Newman's application contained no working examples, *i.e.* specific data regarding actual experiments performed or steps taken to make Newman's chimeras. The nature of his invention was to a new type of chimera never actually made before. Not even primate chimeras had been tried before. The closest combination was goats and sheep.⁴⁹ The prior art showed how to make geeps, but showed much variety in the geeps made.⁵⁰ It did not show methods on how to make their geeps more reproducible.⁵¹ Because of this, the art was very unpredictable. Further, the claims were broadly drawn to a human/non-human primate hybrid with any percentage of cells from each lineage.⁵² There was no specific teaching of any hybrid of any percentage from each lineage. Because of a lack of guidance and presence of working examples, the large amounts of experimentation necessary to produce the invention, and the novelty of the invention in an unpredictable art, the invention claimed in Newman's application would have required undue experimentation to make and use.

The claims in Newman's application were also rejected for lack of written description.⁵³ The inventor is required to show to one of ordinary skill in the art that he or she possesses the claimed invention.⁵⁴ The Examiner asserted that Newman never put down a simple description of an embryo.⁵⁵ In other words, Newman provided methods for how someone might be able to make human/animal chimeras, but besides generally stating that they would have cells from both lineages, little else was described.⁵⁶ This would lead one of ordinary skill in the art to believe that Newman did not possess the invention, in the sense that he had never actually produced the chimeras nor did he have a good idea of what his purported chimeras would be like. From Newman's own statements that he had not actually made the chimeras,⁵⁷ and the variability of the technology relied on to make those chimeras,⁵⁸ it would seem that Newman did not have sufficient written description of his invention for patentability. Newman's claims could have been rejected on this basis, alone.

The claims were also rejected for lack of utility.⁵⁹ Newman asserts ten utilities in his specification.⁶⁰ The Examiner rejected all of them for not being specific, substantial or credible.⁶¹ For example, Newman's most repeated function for his chimeras is that they would be used in toxicology studies. Newman asserted this function as a utility.⁶² The Examiner

⁴⁸ See Newman, *supra* note 3.

⁴⁹ R.L. Gardner, NATURE 220, 596-7 (1968).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² See the specification of U.S.S.N. 08/993,564 at 22-25.

⁵³ 35 U.S.C. § 112 (2000), first paragraph.

⁵⁴ Vas Cath, Inc. v. Marhurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991).

⁵⁵ See *e.g.*, file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004 at 15-17.

⁵⁶ See the specification of U.S.S.N. 08/993,564 throughout, especially at 15, lines 17-21 describing a "strategy" for making the invention.

⁵⁷ Newman, *supra* note 3, at 4.

⁵⁸ See Gardner, *supra* note 46.

⁵⁹ See *e.g.*, file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004 at 10-11.

⁶⁰ Specification of U.S.S.N. 08/993,564, at 14.

⁶¹ See *e.g.*, file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004 at 10-11.

⁶² Newman, *supra* note 3, at 4.

rejected this utility because it was not practical.⁶³ The methods are so general as to be meaningless,⁶⁴ *i.e.* it is unclear what sort of testing Newman would do with these chimeras. It is unclear what advantage using a human/animal chimera that is much like a human would have over testing on humans. Most people would probably be averse to testing on human-like chimeras, and non-human-like chimeras would not make as useful test subjects as humans would. Animal aspects of chimeras could plausibly interfere with the reliability of testing as it pertains to humans. Thus, human testing would still be required to verify results.

The USPTO had no reason to respond to Newman's questioning about the patentability of humans. That determination could be made on a case by case analysis of inventions that would actually have sufficient enablement, written description and utility to be patented. For Newman's application there was no reason that the USPTO had to reach any decision on whether his claims were unpatentable because they "embraced a human": However, rather than simply relying on the above legitimate, albeit mundane, reasons for rejecting Newman's application, the USPTO responded to Newman's provocation and gave him what he wanted by rejecting his claims for "embracing a human".

C. Rejections by the Patent Office for "Embracing a Human"

The USPTO rejected the claims of the Newman application for being drawn to unpatentable subject matter, *i.e.* a human. By doing so the USPTO invented an ambiguous and unwieldy new patentable subject matter rule out of whole cloth. The Examiner stated during the prosecution of Newman's application that despite the ruling in *Chakrabarty*, "For more than 10 years, the USPTO has consistently taken the position that a claim drafted to or including within its scope a human being is not considered patentable subject matter under 35 U.S.C. § 101."⁶⁵ While the Court only seemed to exclude laws of nature, abstract ideas and physical phenomena in *Chakrabarty*, the Examiner stated that the USPTO must judge the patentability in light of the intentions of Congress.⁶⁶ Based on Congressional silence in light of the publicly known policy of the USPTO, Congress did not intend to permit the patenting of humans.⁶⁷ Thus, the Examiner rejected Newman's claims because they "embraced a human," despite being drawn to human/animal hybrids.⁶⁸

Newman responded that there was no statutory support for excluding humans from patentable subject matter.⁶⁹ The Supreme Court in *Chakrabarty* had defined patentable subject matter as anything under the sun made by man.⁷⁰ Further, Newman cited the invalidation of the business method exception, which prevented business methods from being patentable subject matter, in *State Street*.⁷¹ Newman interpreted the making of business methods into patentable subject matter in *State Street* as reiterating the standard for patentable subject matter put forth in

⁶³ See *e.g.*, file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004 at 10-11.

⁶⁴ *Id.*

⁶⁵ *Id.* Office Action mailed on March 18, 1999 at 3.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* Response to Office Action filed on June 16, 1999 at 6-8.

⁷⁰ *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)

⁷¹ *Id.* at 8-9.

Chakrabarty to mean that the Patent Office did not have the authority to limit the patentability of subject matter.⁷² Also, Newman argued that Congress had no intention of protecting human embryos in light of its silence in the face of *Roe v. Wade*,⁷³ thus there was no evidence of Congressional intention to prevent the patenting of humans.⁷⁴

In the subsequent Office Action after Newman's response, the Examiner provided statutory support and support for the USPTO's opinion of the intent of Congress. The Examiner stated that the patenting of a human being would be against the Constitutional right to privacy,⁷⁵ because giving birth to patented human beings would be infringement.⁷⁶ Further, a patent on a human would contradict 37 C.F.R. 271(g) stating that importing products made by a process patented in the United States, is infringement.⁷⁷ This would result in a patented human infringing by leaving and reentering the country.⁷⁸ It would also violate the 13th Amendment of the Constitution, because the patented human being would infringe if he/she attempted to get work against the will of the owner of the patent.⁷⁹

The Examiner responded to Newman's contention that the USPTO did not have the authority to state that humans were not patentable subject matter, by citing *Western Elec. Co. v. Piezo Tech.*,⁸⁰ which stated that the USPTO performs a quasi-judicial function in determining patentability and is regularly called on to interpret the law on a case-by-case basis when reviewing patent applications.⁸¹ Further, the Examiner argued that the reason that Newman's invention, "embraced a human being" was because the specification and claims place no minimum or maximum on the percentage of cells from each of the human and animal in the hybrid.⁸² Thus, these chimeras could be indistinguishable from humans, and thus, embrace them.⁸³

The Examiner's arguments were never challenged on appeal, as Newman recently did not act on his last chance to appeal this case.⁸⁴ However, based on the arguments above, I disagree that the Examiners had clear statutory support for their decision at the time the rejections were first made. Further, while Examiners do have clear statutory support now,⁸⁵ what meaning the term, "human" should take regarding patentability is an open question.

⁷² *Id.*

⁷³ *Roe v. Wade*, 410 U.S. 113 (1973).

⁷⁴ This was before the *Consolidated Appropriations Act of 2004*.

⁷⁵ File History of '564 application, Office Action mailed on October 29, 1999 at 5. *citing* *Griswold v. Connecticut*, 381 U.S. 479 (1965) (law banning use of contraceptives violates right to privacy); *Eisenstadt v. Bard*, 405 U.S. 438 (1971) (government cannot intrude on matters having to do with having a child); *Roe v. Wade* (law forbidding abortion except when life of mother is in danger is unconstitutional).

⁷⁶ File History of '564 application, Office Action mailed on October 29, 1999 at 5.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Western Elec. Co. v. Piezo Tech.* 860 F.2d 428 (Fed. Cir. 1988).

⁸¹ File History of U.S.S.N. 08/993,564, Office Action mailed on October 29, 1999 at 6.

⁸² *Id.* at 6-7.

⁸³ *Id.*

⁸⁴ File History of '564 application, Notice of Abandonment mailed on March 2, 2005.

⁸⁵ *Consolidated Appropriations Act of 2004*, Pub. L. No. 108-199, § 634, 118 Stat. 101.

II. No specific statutory support was available to disallow the patentability of claims drawn to humans and human embryos.

Despite claims by Newman that the technology existed, at least potentially, to produce his invention of human chimeras,⁸⁶ there had not been any statutes passed concerning its regulation from a patentability perspective. There are two legal doctrines that, in the past, have been used to determine the patentability of certain ethically questionable subject matter. The Moral Utility Doctrine, first propounded by Justice Story in 1817, prevented patents to immoral inventions.⁸⁷ This doctrine has been unused of late, due to the problematic nature of determining what is immoral, and the specter of the federal government imposing police power upon the States through the patent laws.⁸⁸ While mentioned during the prosecution of the Newman application, this doctrine does not lend statutory support to the blocking of human/animal chimeras as patentable subject matter. The other doctrine is 35 U.S.C. § 101, which determines patentable subject matter. The Supreme Court, in *Chakrabarty* most recently, determined that this statute was very open ended, meaning that anything made by man was patentable, leaving little support for the non-patentability of humans.⁸⁹ When there is no statutory support, the USPTO then may interpret the patentability of new subject matter in light of the intent of Congress or to fit in the larger statutory scheme.⁹⁰ As with the above-mentioned doctrines, Congressional intent, based on the larger statutory scheme, did not, at the time of the Newman application, give support for the non-patentability of humans.

A. Moral Utility Doctrine.

In *Lowell v. Lewis*, Justice Story first mentioned the Moral Utility Doctrine stating that inventions that are, “injurious to the well-being, good policy, or sound morals of society” are unpatentable.⁹¹ Justice Story defines the term “useful” as the antonym of “mischievous or immoral.”⁹² In the past, the moral utility doctrine has been used to forbid the patenting of gambling machines.⁹³ However, this doctrine has not been used as broadly recently. For example, patents to gambling machines held to be unpatentable in *Brewer v. Lichtenstein*, were held patentable, years later, in *In re Murphy*.⁹⁴

Moreover, even while the moral utility doctrine was in full force, for a patent to be held invalid under it, the invention patented could have only immoral uses. For example, in *Fuller v.*

⁸⁶ See the Background of the Invention in the specification of U.S.S.N. 08/993,564.

⁸⁷ *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D.Mass. 1817).

⁸⁸ *Webber v. Virginia*, 103 U.S. (13 Otto) 344, 347-348 (1880) (holding “Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted”).

⁸⁹ *Diamond v. Chakrabarty*, 447 U.S.303, 309 (1980).

⁹⁰ See the File History of U.S.S.N. 08/993,564 application, non-final Office Action mailed on January 29, 2003 at 27, (construing *DeBartolo Corp., v. Florida Gulf Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988)).

⁹¹ *Lowell*, 15 F. Cas. at 1019.

⁹² *Id.*

⁹³ *Brewer v. Lichtenstein*, 278 F. 512 (7thCir. 1922) (patent invalid because only utility of machine patented is to appeal to gambling instinct of customers); *Nat’l Automatic Device Co. v. Lloyd*, 40 F. 89 (C.C. Ill. 1889), (patent invalid because horse race machine can only be used for gambling).

⁹⁴ *In re Murphy*, 200 USPQ 801 (PTO Bd.App.1977).

Berger,⁹⁵ a patent drawn to a slot that detected false coins was held invalid even though it could be used, and often was used, on gambling machines.⁹⁶ On appeal, the court reasoned that a Colt's revolver is an instrument of death, but would still allow a patent on it, if it were shown to the court that, "the instrument were susceptible to good uses."⁹⁷

More recently in *Juicy Whip, Inc. v. Orange Bang, Inc.*⁹⁸ the court stated that the moral utility doctrine had not been applied for years.⁹⁹ In *Juicy Whip*, a patent to a drink dispenser with a display which falsely showed the drink being mixed in the display was held to be valid.¹⁰⁰ Two cases were cited in *Juicy Whip*, wherein patents drawn to inventions that imitated more expensive products were invalidated using the moral utility doctrine. In *Rickard v. Du Bon*,¹⁰¹ the court held that a patent drawn to a process of spotting tobacco was unpatentable when the spotting was only applied to make a less expensive and less sought after tobacco look like a more sought after variety. In *Scott & Williams v. Aristo Hosiery*¹⁰² the court held that a patent drawn to stockings with a false seam, which made the stockings look like higher quality stockings, was invalid under the moral utility doctrine.¹⁰³ The court in *Juicy Whip* overruled these cases, stating that there was utility in making less expensive versions of products, and that this has been considered the case in patent law for years.¹⁰⁴

The moral utility doctrine has never been applied to biotechnology cases. In *Diamond v. Chakrabarty*, the Supreme Court held that bacteria changed by scientists to be more efficient at digesting oil were patentable, despite the fact that organisms were not specifically defined as patentable subject matter by the utility statute.¹⁰⁵ The moral utility doctrine is not mentioned in *Chakrabarty*; despite the fact that the invention at issue was controversial at the time. The only issue in *Chakrabarty* was whether Congress intended 35 U.S.C. § 101,¹⁰⁶ the statute which defines patentable subject matter, to cover genetically modified organisms.¹⁰⁷ Later, other transgenic animals including mammals like mice¹⁰⁸ were held to be patentable as well with no moral objections. Thus, at least, non-human animals are patentable with no moral restrictions. The court suggested in *Chakrabarty* that moral questions about biotechnology inventions should be left for Congress to decide.¹⁰⁹

It seems that the moral utility doctrine has disappeared from patent law in the United States. However, it may still be good law in certain extreme situations. The doctrine would not

⁹⁵ *Fuller v. Berger*, 120 F. 274 (7th Cir. 1903).

⁹⁶ *Id.* at 276.

⁹⁷ *Id.*

⁹⁸ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364 (Fed. Cir. 1999).

⁹⁹ *Id.* at 1366-67.

¹⁰⁰ *Id.* at 1365.

¹⁰¹ *Rickard v. Du Bon*, 103 F. 868 (2d Cir. 1900).

¹⁰² *Scott & Williams v. Aristo Hosiery Co.*, 7 F.2d 1003 (Fed. Cir. 1925).

¹⁰³ *Juicy Whip, Inc.*, 185 F.3d at 1367.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 318.

¹⁰⁶ "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

¹⁰⁷ *Diamond v. Chakrabarty* 447 U.S. 303, 309 (1980).

¹⁰⁸ *The Harvard Mouse*, U.S. Patent No. 4,736,866 (filed June 22, 1984).

¹⁰⁹ *Chakrabarty*, 447 U.S. at 304.

prevent the patenting of humans or human embryos on its own if they were held to have some legitimate use, *e.g.* the Colt revolver described above, had moral utility because it could be used in self defense, not merely as a tool of destruction. Insofar as cloned humans or human embryos have some legitimate utility, they would not be subject to the moral utility doctrine. Since the Examiner rejected the utilities asserted by Newman, it would have been consistent to use the moral utility doctrine, although still unnecessary and controversial.

The only time the USPTO mentions the moral utility doctrine is in one Office Action.¹¹⁰ The Examiner stated, in the January 2003 Office Action that before “useful” was defined by 35 U.S.C. § 101, it had been construed to exclude frivolous or injurious inventions that were counter to the good morals of society.¹¹¹ The Examiner asserted that the question whether humans should be the subject to patent protection, “raises grave issues going to the core of what a useful invention is.”¹¹² However, the Examiner does not go on to judge inventions drawn to humans as being immoral. The Examiner mentioned the Moral Utility Doctrine, but never actually asserted it alone.

It is unclear what this means for the Moral Utility Doctrine. If there was a condition under which the Doctrine should still be applied, this was the condition. Newman did not assert any substantial utility for his chimeras, and one could argue that these creatures would not have any legitimate use. Because the Doctrine was not directly used by the Examiner to reject Newman’s claims, perhaps the Moral Utility Doctrine has fused with the rules regarding patentable subject matter; excluding Examiners from making moral judgments regarding what should be patentable subject matter and requiring a broad interpretation of what is patentable, absent other factors.

B. Patentable Subject Matter

Patentable subject matter has been interpreted broadly by the courts in biotechnology cases. In *Chakrabarty* the Supreme Court ruled that patentable subject matter included anything under the sun made by man.¹¹³ The Federal Circuit cited this passage of *Chakrabarty* in *State Street*.¹¹⁴ The patent in question in *State Street* was drawn to a business method, which, it was asserted, was not statutory subject matter under 35 U.S.C. § 101.¹¹⁵ The court ruled that the use of the word “any” in 35 U.S.C. § 101 shows Congress’ intent not to place any restrictions on the subject matter for which a patent may be obtained.¹¹⁶ The court further held that the exception of business methods in patentable subject matter had never been created by the courts and that its removal from the Manual of Patent Examining and Procedures (MPEP), verified that business methods were patentable subject matter.¹¹⁷

¹¹⁰ File History of U.S.S.N. 08/993,564, Office Action mailed on January 29, 2003.

¹¹¹ *Id.* Office Action mailed on January 29, 2003 at 28.

¹¹² *Id.*

¹¹³ *Chakrabarty supra* note 70.

¹¹⁴ *State St. Bank & Trust v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

¹¹⁵ *Id.* at 1373.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 1377.

The courts have even recently held that patentable subject matter should be broadly construed. Thus, absent the continuing existence of a strong Moral Utility Doctrine, humans and human embryos should be patentable subject matter, based on the above precedent, insofar as they are made by man and are novel.

C. Intent of Congress

The USPTO interprets the law in light of the intent of Congress, despite the difficulty in ascertaining this intent.¹¹⁸ The Patent Office had stated in 1987 that they had no intention of patenting humans.¹¹⁹ The Congress amended the patent statutes many times between 2003 and 1987. If they wanted to allow patents to humans, they could have specifically made amendments to the laws that would allow them.¹²⁰ Further, the subject matter is contentious, and the USPTO did not want to step into the shoes of the Congress in making such an important decision.¹²¹

Arguably, Congress had declared its intent regarding patent protection on claims drawn specifically to humans by never passing legislation undoing Supreme Court decisions regarding reproductive privacy.¹²² The birth of a patented near human could potentially be an act of patent infringement,¹²³ but the enforcement of this infringement could interfere with the mother's right to privacy.¹²⁴ Also, the 13th Amendment forbidding slavery would also conflict with patent rights on a human. A patented human being would not be able to gain employment, because such an employment would be an infringing use.¹²⁵ However, Congress' intent could be interpreted as allowing claims drawn to human chimeras and only enforcing these claims insofar as was Constitutional.

In light of Congress' passing of the Consolidated Appropriations Act of 2004, Congressional intent seems obvious now, but at the time of Newman's application it was difficult to say for sure what Congress' intent was from its previous lack of legislation in this area. However, the intent of Congress was what the Patent Office relied on primarily to reject humans and human embryos as patentable subject matter in Newman's application. There were many uncertainties in the law on which the Examiners relied in rejecting patents embracing humans. It almost seems as if there was a policy decision made at the higher levels of the USPTO to prevent the patenting of humans, which was later translated into the amendment of the Consolidated Appropriations Act of 2004 to prohibit patenting of human organisms. However,

¹¹⁸ See 35 U.S.C. § 131 (2000) (responsibility of USPTO to decide whether an applicant is entitled to a patent under law) and *FDA v. Brown & Williamson Tobacco Corp.*, 120 S.Ct. 1291 (2000) (when Congress does not specifically address a question of statutory interpretation the statutory provision should be interpreted with a view to its place in the overall statutory scheme).

¹¹⁹ *Id.* at 29.

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *E.g.* *Griswold v. Connecticut*, 381 U.S. 479 (1965).

¹²³ See 35 U.S.C. § 271(a) (2000).

¹²⁴ *Roe v. Wade*, 410 U.S. 113, 114 (1973). If a mother has a right to privacy in terminating her pregnancy, she would seem to have a right to privacy if she chose to have the baby despite potential patent infringement.

¹²⁵ See 35 U.S.C. § 271(a) and R. Weiss, *U.S. Denies Patent for a Too-Human Hybrid*, WASHINGTON POST, Feb. 13, 2005, at A3. Employment may be considered a use of the patented invention (the organism) by the organism itself in employment. Prevention of a person from working, except for the patentee, would amount to slavery or involuntary servitude forbidden by the 13th Amendment of the Constitution.

as shown below, interviews with at least one of the higher ups, this may have been a more personal vendetta than an imposition of a policy against claims embracing humans.

III. The politics of human patenting and the consequences of the rejection of Newman's claims

In the case of Newman's application, there was clearly no need to invoke a ban on human patents. If the USPTO wanted to avoid the question altogether, it easily could have. It is difficult to say why it did not. Former Commissioner Lehman, who stated there would be no patents on "monsters", explained that his problem was more with the Newman application in particular than patents on "humans" in general.¹²⁶ Lehman said, "Stuart Newman is promoting an effort that will make it difficult to engage in biological research and commercialize the fruits of that research. It's not funny or cute; it is profoundly wrong. Every attempt to stop science has been characterized by darkness."¹²⁷ Lehman also stated that if Geron or Advanced Cell Technology or almost any biotech firm applied for the same patent that Newman did, he would not have stood in their way.¹²⁸ He does not believe that there should be a prohibition of a patent on a human.¹²⁹ Lehman spoke of his motivation for his "monsters" comment. "I was just deeply offended by anyone attempting to use the U.S. Patent Office to make a point, or to stop the advancement of science. I refused to make it easy for him."¹³⁰

Easy or not, Newman did make a point using the USPTO. After his most recent Office Action, rejecting his claims, and after the passage of the Consolidated Appropriations Act of 2004, Newman declined to continue prosecution. Newman did get an Examiner to state that claims that, "embrace a human" are unpatentable, but it is unclear what this really means.

Newman's claims "embraced a human" because his chimeras were defined to contain any percentage of human and animal cells. The claims, as finally amended (and rejected), were only drawn to chimeric embryos, but these were also held to be unpatentable as embracing humans.¹³¹ Thus, as long as the embryo from which an organism was generated contained any amount of human and animal cells, and the adult derived from this embryo also contained any amount of human and animal cells, this would be a chimera under Newman's claims. Thus, the claims encompassed, *e.g.* a human who contained one chimpanzee cell, as long as the one chimpanzee cell originated in the human's embryo. So, Newman's claims contained *de facto* humans within their scope and this was the basis of the rejection by the USPTO.¹³²

The unpatentability of Newman's claims would not have changed under the Consolidated Appropriations Act of 2004. Humans remain unpatentable, but the question remains of what constitutes a human? Clearly, the broad scope of Newman's claims encompassed a human. It is hard to believe that a human with one chimpanzee cell in him/her would be any different from a

¹²⁶ Dowie, *supra* note 30.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ See File History of U.S.S.N. 08/993,564, Response filed on February 9, 2004.

¹³² *Id.* Final Office Action filed on August 2, 2004, at 20.

human without this cell. However, Newman's claims also encompassed chimeras which would have been very non-human, such as a chimpanzee containing one human cell.

A more complicated question would have arisen with a claim that had a bottom limit on percentage of animal cells or a ceiling on percentage of human cells in a chimera. Then it would have been less clear whether the embryos or resultant organisms embraced humans. Another option a future patentee may have is throwing the USPTO's language back at them, drafting a claim to a chimera specifically stating the chimera does not embrace a human. In a sense, by putting the patentability of claims in terms of a confusing definition, like "human", the USPTO and Congress have made it even less clear what is patentable and what is not. By using it here, the Patent Office has created some small amount of precedent (now that this case has had some publicity) that it will not allow claims embracing humans, but has made absolutely no statement as to the limits of that embrace.

Ultimately, the USPTO ruling in the Newman case and the subsequent legislation pushes back any real decision on the question of patentable subject matter. The codification of the rule of no patenting of humans simply puts forth the question of what is a human, and how much genetic engineering of a human would it take to make a human no longer a human. This question will depend on the nature of any chimeras made in the future, if any, and the values of the society that exists at that time. In a sense, the Newman case was much ado about nothing.

Further, the Newman application did a disservice by foisting an abstract and vague ethical dilemma upon the USPTO. Newman did not actually have any chimeras, and therefore had no idea what they might be used for. Newman puts forth this idea that somehow, human/animal chimeras would be excellent subjects for toxicology studies, but never explains why.

Any true ethical debate, if it is to be an actual debate, needs to provide logical reasons for acting, and not acting. Newman's chimeras have no commercial reason to exist yet. So, unless motivated by self-righteousness, no applicant would bother to waste their money on the application. The real ethical dilemma will be when someone actually invents a chimera that has usefulness that is both human-like and animal-like. What if creating a very human-like human/animal chimera creates a cure to AIDS? How many chimeras can one justify to create a cure? Newman would argue that the Patent Office should stay entirely away from this subject area to prevent scientists from researching on organisms that would cause these sorts of ethical dilemmas. However, there may be sound ethical reasons for sacrificing one chimera to save millions, depending on the characteristics of the chimera and the characteristics of the potential victims. This is a dilemma for neither Newman nor the Patent Office to dictate, but one that requires broader public debate and consensus.

Newman is scaremongering. Newman wows the uninitiated with technological jargon, making them think that common sense could not possibly be brought to bear on the subject. For example, in his article in *Medical Ethics*, Newman explains the difficulty of drawing a line between patented invention like bone marrow stem cells and pigs with human genes and other, obviously troublesome inventions.¹³³ Newman asserts that drawing this line may be an

¹³³ Newman, *supra* note 3 at 7.

impossible task, because of the common evolutionary heritage of organisms on earth, positing that, “we share more than 98 percent of our DNA sequence with chimpanzees, for example.”¹³⁴ But this assertion muddies the issue instead of clarifying it.

The sequences of the coding regions of genes in humans and chimpanzees (and other primates) are similar. However, from an ethical standpoint, this really means very little. Our common ancestor shared with chimpanzees existed a shorter time ago than our common ancestors with other organisms. That said, one can tell by just observing chimps that while they have some similarities with humans and that there are obvious differences. Whether the gene sequences of chimps and humans are 50% identical, 98% identical or 99% identical is irrelevant. What are relevant are the traits of the organism. No additional scientific jargon or irrelevant data is necessary to make an ethical decision regarding them. There is opposition to performing medical tests on higher primates because they are very human like, just as there would be an opposition to the abuse of human/animal chimeras or any other quasi-human engineered that was also human like. However, without a specific chimera, there can be no ethical debate.

The Patent Office should not have rejected Newman’s claims because they embraced a human, thus possibly triggering the passage of the amended Consolidated Appropriations Act of 2004. Firstly, Newman’s claims were so thoroughly rejected, without recourse to the “embracing a human” rejection, that there was no reason to think from the first Office Action, that any claim would be allowed. The MPEP suggests that Examiners should spell out all rejections up front so that no more than one non-final Office Action need be submitted,¹³⁵ but the “embracing a human” rejection here, is reaching. There was no danger of piecemeal examination, thus the policy decision could have been withheld until a proper application presented a real ethical problem.

Even if another inventor files an application on an invention which embraces a human, he or she would not be able to enforce claims embracing humans. The inventor could enforce his rights up until the point they were deemed unconstitutional. Under the canon of constitutional avoidance, when “a statute is susceptible to two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, [a court’s] duty is to adopt the latter.”¹³⁶ Thus, in the situations cited by the Examiner described above, for example, when a patented chimera left and returned to the country, or got employment, the infringement statute would not apply. This is because the court should interpret the statute to include exceptions to infringement that are protected by the Constitution. However, for example, if someone made a chimera for commercial purposes, they would still be deemed to infringe.

If the worry is that human experimentation would take place during an attempt to develop human cloning, drafting a law to simply make this experimentation illegal would be much more effective than only making it unpatentable. With the current legislation, inventors may use genetically modified organisms which should be considered to embrace humans in their experiments, for example, to make patentable organisms which do not resemble humans.

¹³⁴ *Id.*

¹³⁵ MPEP 707.07(g) Piecemeal Examination

¹³⁶ *United States ex rel. Attorney Gen. v. Delaware & Hudson Co.*, 213 U.S. 366, 408 (1909).

A patent can only give value to an invention if there is a commercial market for it. It is hard to see how there would be a commercial market for a cloned human or human/animal chimera at this time. As for the hybrids encompassed by Newman's claims, they do not exist but the technology, arguably, exists to make them. If there is such great demand or need for them, why have they not been invented in reality as opposed to in Newman's imagination? Perhaps human/animal chimeras will prove extremely useful in the future. If they do, then the issue should be dealt with when this happens, having all the facts in hand.

Since the development of nuclear weapons, there has been a push to think about what should be invented instead of what can be invented. The novels of Michael Crichton warn us of the dangers involved in the development of everything from extraterrestrial bacteria¹³⁷ to genetically engineered dinosaurs,¹³⁸ much as Shelley's *Frankenstein* warned of the activities of grave robbing maniacal scientists. One wonders how we dare try to invent anything at all. However, generally, if there is a desire or need for an invention it will eventually be made. Certainly, genetic manipulation of humans presents as many different ethical problems as nuclear energy does, but these problems will never be developed unless the technology is. There is little danger of the promulgation of a race of ape/men subjugated to experimentation, but there are more probable ethical problems which genetic engineering could cause. Genetic manipulation may one day lead to genetically enhanced human offspring.¹³⁹ Technology may advance to develop biological androids much like humans, which may be just different enough to be hunted and destroyed.¹⁴⁰ A device may be developed to convince a small group of people to stage an invasion of the earth from Mars to unify the world, and bring world peace.¹⁴¹ While it is possible to project what the ethical response may be to these technologies, it is impossible to see into the future and see how the technologies will integrate into the societies of the future or what ethical problems they will present. Thus, we should wait until then before we make judgments about them based on works of fiction -- both literary and laboratory.

¹³⁷ MICHAEL CRICHTON, *THE ANDROMEDA STRAIN* (Avon Books 2003) (1971).

¹³⁸ MICHAEL CRICHTON, *JURASSIC PARK* (Ballantine Books 1993) (1991).

¹³⁹ *GATTACA* (Columbia/Tristar Studios 1997).

¹⁴⁰ PHILIP K. DICK, *DO ANDROIDS DREAM OF ELECTRIC SHEEP?* (Del Rey 1996) (1968).

¹⁴¹ KURT VONNEGUT JR., *THE SIRENS OF TITAN* (Delta 1998) (1959).